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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Y2121	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB 03/04846	International filing date (day/month/year) 10.11.2003	Priority date (day/month/year) 14.11.2002
International Patent Classification (IPC) or both national classification and IPC A61B5/087		
Applicant NUTREN TECHNOLOGY LIMITED et al.		

1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.
 - This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 10 sheets.

3. This report contains indications relating to the following items:
 - I Basis of the opinion
 - II Priority
 - III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV Lack of unity of invention
 - V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI Certain documents cited
 - VII Certain defects in the international application
 - VIII Certain observations on the international application

Date of submission of the demand 24.04.2004	Date of completion of this report 28.01.2005
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International application No. PCT/GB 03/04846

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1, 2, 4-7, 9-17 as originally filed
3, 3a, 8 received on 13.08.2004 with letter of 11.08.2004

Claims, Numbers

1-36 received on 13.08.2004 with letter of 11.08.2004

Drawings, Sheets

1/2-2/2 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

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5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	9,16-21,34
	No: Claims	1-8,10-15,22-33,35,36
Inventive step (IS)	Yes: Claims	9,34
	No: Claims	1-8,10-33,35,36
Industrial applicability (IA)	Yes: Claims	1-36
	No: Claims	

2. Citations and explanations

see separate sheet

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Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US 2002/0062069 A (MAULT J R) 23 May 2002 (2002-05-23)
D2: WO 01/08554 A (HEALTHETECH INC) 8 February 2001 (2001-02-08)

The documents were not cited in the international search report.

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1 - 8, 10 - 15, 22 - 25** is not new in the sense of Article 33(2) PCT.

- 2.1. The document D1 discloses (the references in parentheses applying to this document):

A respiratory calorimeter (10 in FIG. 5; Note: The term "a breath monitoring device in the form of a calorimeter" is not clear and construed as a respiratory calorimeter) comprising

- means to record a first breath parameter of calories expended by a user (52 in FIG. 5; paragraphs 50, 51; Note: It is not clear what a "breathing state of calories expended" shall refer to. Therefore, this feature is construed as being directed to a breath parameter of calories expended), and
- means to detect a deviation from the recorded breath parameter in a subsequent use of the device by a user (cf. paragraph 63, the software running on PDA 52 in FIG. 5 detects changes in RMR measurements).

The subject-matter of **claim 1** is, therefore, anticipated by the disclosure of document D1.

- 2.2. The supplementary features introduced in dependent **claims 2-8, 10-15, 22-25** are also already anticipated by document D1, see in particular FIG. 5, paragraphs 47 and 51.

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3. Dependent claims 16 - 21 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33 (3) PCT), the reasons being as follows:

The detection of a too high flow rate and stop of operation of the device in such a case is already known from the respiratory calorimeter disclosed in document D2, cf. page 50, lines 4-15. It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a respiratory calorimeter according to document D1, thereby arriving at a respiratory calorimeter according to claims 16-21.

4. The combination of the features of dependent claim 9 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:

4.1. The document D1, which is regarded as being the closest prior art to the subject-matter of claim 9, discloses a breath monitoring device comprising the features of claim 1, see point 2.1 above.

4.2. The subject-matter of claim 9 differs from this known device in that the means to detect a deviation from the recorded breath parameter (cf. point 2.1 above for interpretation of the unclear features) comprises means to detect when a user other than the first user uses the device.

4.3. The subject-matter of claim 9 is therefore new (Article 33(2) PCT).

4.4. The problem to be solved by the present invention may be regarded as to provide a breath monitoring device which is capable of monitoring the breathing state of more than one user over a period of time.

4.5. The solution to this problem proposed in claim 9 is neither disclosed nor suggested in any of the documents cited in the international search report. As a consequence, the subject-matter of claim 9 is considered as involving an inventive step (Article 33(3) PCT).

5. When operating, the device of document D1 carries out the method as defined in independent method claim 26 and dependent claims 27-33, 35, and 36, see the

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passages cited in point 2 above. The subject-matter of **claims 26 - 33, 35, and 36** is, therefore, also not new in the sense of Article 33(2) PCT.

6. The combination of the features of dependent **claim 34** is neither known from, nor rendered obvious by, the available prior art. The reasoning set out above in point 4 applies *mutatis mutandis* to the method defined in claim 34.

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problems of the prior art, whether expressly described hereinabove or not.

Summary of the Invention

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According to a first aspect of the invention there is provided a breath monitoring device in the form of a calorimeter comprising means to record a first breathing state of calories expended by a user, and means to detect 10 a deviation from the recorded breathing state in a subsequent use of the device by a user.

Preferably the calorimeter is a direct or an indirect calorimeter.

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Suitably the calorimeter comprises a housing in which the recording means and detection means are located.

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Suitably the means to record a first breathing state of a user comprise means to record at least one furtherbreath parameter of a user in addition to calories expended. Preferred breath parameters which may be recorded include at least one parameter selected from calories expended between breaths, calories expended over a defined time period, inhalation speed, exhalation speed, inhalation volume, exhalation volume, oxygen content of exhaled breath, carbon dioxide content of exhaled breath, time interval between breaths, number of breaths in a predetermined time period, duration of an exhalation, 25 duration of an inhalation and the rate of change of any of 30 the aforementioned parameters.

3a

Thus, suitable means to record a first breathing state of a user may be one or more means selected from an inhalation speed sensor, an exhalation speed sensor, an

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According to a second aspect of the present invention there is provided a method of monitoring breaths, the method comprising the steps of:

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- (a) recording a first breathing state of calories expended by a person from a breath of a person;
- (b) detecting a deviation form the recorded first breathing state in a subsequent breath from a person.

10

Step (a) may comprise recording a first breathing state determined from a plurality of breaths from the person.

15

Step (a) may comprise monitoring at least one further breath parameter of the person's breath. Preferred breath parameters include at least one parameter selected from calories expended between breaths, calories expended over a defined time period, inhalation speed, exhalation speed, inhalation volume, exhalation volume, oxygen content of exhaled breath, carbon dioxide content of exhaled breath, time interval between breaths, number of breaths in a predetermined time period, duration of an exhalation, duration of an inhalation and the rate of change of any of the aforementioned parameters.

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Suitably step (b) comprises comparing one or more subsequent breaths of a person with the first breathing state recorded from the or each breath recorded in step (a).

Suitably there is a step between step (a) and (b) of storing data obtained from the recordal of the first

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CLAIMS

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1. A breath monitoring device in the form of a calorimeter comprising means to record a first breathing state of calories expended by a user, and means to detect a deviation from the recorded breathing state in a subsequent use of the device by a user.
5
- 10 2. A breath monitoring device as claimed in claim 1 comprising a housing in which the recording means and detection means are located.
- 15 3. A breath monitoring device as claimed in claim 1 wherein the means to record a first breathing state of the user comprises means to record at least one further breath parameter of a user in addition to calories expended.
- 20 4. A breath monitoring device as claimed in claim 3 wherein the or each further breath parameter is selected from inhalation speed, exhalation speed, inhalation volume, exhalation volume, oxygen content of exhaled breath, carbon dioxide content of exhaled breath, time interval between breaths, number of breaths in a predetermined time period, duration of an exhalation, duration of an inhalation and the rate of change of any of the aforementioned parameters.
25
- 30 5. A breath monitoring device as claimed in claim 4 wherein the means to record the further breath parameter is one or more means selected from an inhalation speed sensor, an exhalation speed sensor,

an inhalation volume sensor, an exhalation volume sensor, an inhalation duration sensor, an exhalation duration sensor, an inhalation pressure sensor and an exhalation pressure sensor.

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6. A breath monitoring device as claimed in claim 1 wherein the means to record a first breathing state of a user comprises means to record an unforced breathing state.

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7. A breath monitoring device as claimed in claim 6, wherein the unforced breathing state is a resting breathing state or the breathing state of the user after physical activity or exertion.

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8. A breath monitoring device as claimed in claim 1, wherein the means to detect a deviation from the first breathing state preferably comprises the means to record the first breathing state.

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9. A breath monitoring device as claimed in claim 1, wherein the means to detect a deviation from the first breathing state comprises means to detect when a user other than the first user uses the device.

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10. A breath monitoring device as claimed in claim 1, wherein the device further comprises means to store data obtained from the first breathing state recordal means.

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11. A breath monitoring device as claimed in claim 1, wherein the data storage means comprises a machine

readable medium, on which data may be stored by any suitable means.

12. A breath monitoring device as claimed in claim 11,
5 wherein the data storage means comprises a computer hard disk, chip-based memory, floppy disk, compact disc, DVD (digital versatile disc), or mini-disc.
13. A breath monitoring device as claimed in claim 1,
10 wherein the device further comprises indicating means, arranged to indicate when a deviation from the first breathing state is detected by the deviation detection means.
14. A breath monitoring device as claimed in claim 13,
15 wherein the indicating means is a visual indicating means, audio indicator means, or both visual and audio indicator means.
15. A breath monitoring device as claimed in claim 14,
20 wherein the indicating means is capable of displaying the extent of the deviation of the or each breath parameter which does not conform to the or each breath parameter of the first breathing state.
16. A breath monitoring device as claimed in claim 1,
25 comprising means to temporarily prevent operation of the device by a user, when a deviation from the first breathing state is detected.
17. A breath monitoring device as claimed in claim 16,
30 wherein the device operation prevention means prevents operation for a defined time period.

18. A breath monitoring device as claimed in claim 16,
wherein the device operation prevention means
comprises a switch or trigger which is activated when
5 the deviation detection means detects a deviation from
the first breathing state.
19. A breath monitoring device as claimed in claim 16,
wherein the device operation prevention means prevents
10 subsequent breaths by a user from entering the device,
or prevents recordal of subsequent breaths by the
recordal means.
20. A breath monitoring device as claimed in claim 1
15 further comprising means for a user to accept or
decline a breath recordal, whether a breath is within
the parameters of the first breathing state or is a
deviation from the first breathing state.
- 20 21. A breath monitoring device as claimed in claim 20,
wherein the breath recordal acceptance means comprises
a switch which in use must be activated to accept a
breath reading in order for the reading to be recorded
by the means to record the first breathing state of a
25 user.
22. A breath monitoring device as claimed in claim 1
comprising a fluid inlet, which in use is arranged to
allow passage of a users breath into and out of the
30 device.
23. A breath monitoring device as claimed in claim 22,
wherein the fluid inlet comprises a mouthpiece.

24. A breath monitoring device as claimed in claim 23, wherein the mouthpiece is detachably connected to the fluid inlet.

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25. A breath monitoring device as claimed in claim 23, wherein the mouthpiece comprises a mask arranged in use to be placed over at least the mouth of a user.

10 26. A method of monitoring breaths, the method comprising the steps of:

(a) recording the first breathing state of calories expended by a person, from a breath of a person;
15 and

(b) detecting a deviation from the recorded first breathing state in a subsequent breath from a person.

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27. A method as claimed in claim 26, wherein step (a) comprises recording a first breathing state determined from a plurality of breaths from the person.

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28. A method as claimed in claim 26, wherein step (a) comprises monitoring at least one further breath parameter of the persons breath in addition to calories expended.

30 29. A method as claimed in claim 28, wherein the further breath parameter is at least one parameter selected from inhalation speed, exhalation speed, inhalation volume, exhalation volume, oxygen content of exhaled

breath, carbon dioxide content of exhaled breath, time interval between breaths, number of breaths in a predetermined time period, duration of an exhalation, duration of an inhalation and the rate of change of
5 any of the aforementioned parameters.

30. A method as claimed in claim 26, wherein step (b) comprises comparing one or more subsequent breaths of a person with the first breathing state recorded from
10 the or each breath recorded in step (a).
31. A method as claimed in claim 26, wherein there is a step between step (a) and (b) of storing data obtained from the recordal of the first breathing state of the
15 person in step (a).
32. A method as claimed in claim 26, wherein step (b) comprises detected a deviation from the stored data.
- 20 33. A method as claimed in claim 26, wherein step (b) may comprise detecting a deviation from a subsequent breath or breaths originating from the same person as step (a), or from a different person.
- 25 34. A method as claimed in claim 33, wherein the method comprises distinguishing between a first breathing state of a first person and a breathing state of a second person.
- 30 35. A method as claimed in claim 26 comprising a step (c) of indicating when a deviation has been detected.

36. A method of monitoring breaths as claimed in claim 26,
using a breath monitoring device as claimed in claim
1.